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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

BA
Application No.

10/069,827

Applicant(s)

DERAND ET AL

Examiner

Jeffrey T. Barton

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 and 38-53 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-36 and 38-53 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 20050202.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed on 2 February 2005 does not place the application in condition for allowance.

Status of Objections and Rejections Pending Since the

Office Action of 23 September 2004

2. The objections to claims 2, 11, 13, 19, 22, 33, and 35 are withdrawn due to Applicants' amendment.
3. The rejection of claim 7 under 35 U.S.C. §112(2) is withdrawn due to Applicants' amendment that fluid entry is by self-suction, defined as capillary forces in the specification. (Page 14, lines 20-24)
4. The rejection of claim 30 under 35 U.S.C. §112(2) is withdrawn due to Applicants' amendment.
5. The rejection of claim 37 under 35 U.S.C. §112(2) is withdrawn due to cancellation of the claim.
6. The rejection of claims 1-6, 8, 10, 11, 18-23, 28, 31-36, and 38-41 under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Amigo is maintained.
7. The rejection of claim 7 under 35 U.S.C. §103(a) as obvious over Amigo in view of Zimmer et al is maintained.

8. The rejection of claim 9 under 35 U.S.C. §103(a) as obvious over Amigo in view of Regnier et al is maintained.
9. The rejection of claims 12, 13, and 29 under 35 U.S.C. §103(a) as obvious over Amigo in view of Karger et al is maintained.
10. The rejection of claims 14 and 24-26 under 35 U.S.C. §103(a) as obvious over Amigo in view of Bergstrom et al is maintained.
11. The rejection of claims 15-17 under 35 U.S.C. §103(a) as obvious over Amigo in view of Malmsten et al is maintained.
12. The rejection of claims 1 and 27 under 35 U.S.C. §103(a) as obvious over Karger et al in view of Van Alstine is maintained.
13. The rejection of claims 1 and 30 under 35 U.S.C. §103(a) as obvious over Regnier et al in view of Amigo is maintained.

Previous Claim Rejections - 35 USC § 102

14. Claims 1-6, 8, 10, 11, 18-23, 28, 31-36, and 38-41 are rejected under 35 U.S.C. 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Amigo.

Addressing claim 1, Amigo discloses a microfluidic device (Column 6, line 46 - Column 8, line 21) comprising a set of one or more (Column 7, lines 29-34) covered microchannel structures (Column 7, lines 49-55) manufactured in the surface of a planar substrate (Column 3, line 36 - Column 4, line 9), wherein non-specific adsorption and hydrophilicity are optimized by a coat exposing a non-ionic hydrophilic polymer on a part

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of the surface of at least one of the microchannel structures. (Column 4, line 53 - Column 5, line 48) Also regarding the question of optimization, generally, differences in concentration (i.e. in this case, density, thickness, or other variable of the coating) or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Addressing claim 2, Amigo discloses the surface carrying the coat being made of organic material. (Column 3, line 36 - Column 4, line 22)

Addressing claim 3, Amigo discloses the surface of the planar substrate being made of plastic. (Column 4, lines 10-22)

Addressing claims 4 and 20, Amigo discloses the non-ionic hydrophilic polymer being attached to a polymer skeleton that is attached to the surface. (Column 4, lines 10-64)

Addressing claim 5, Amigo discloses the device comprising more than five covered microchannel structures. (Column 7, lines 29-31)

Addressing claim 6, Amigo discloses microchannel structures that comprise conduits for liquid transport. (Column 4, line 65 - Column 5, line 3)

Addressing claim 8, Amigo discloses microchannel structures comprising a microcavity having a volume less than or equal to 1 μL . (Column 6, line 60 - Column 7, line 14; usual microchannel dimensions give a volume range of 0.02 - 2.5 μL)

Addressing claim 10, Amigo discloses the device being a round disk. (Column 7, lines 20-25)

Addressing claim 11, Amigo discloses the hydrophilic polymer comprising amide or ethylene oxy groups. (Column 5, lines 32-40)

Addressing claims 18 and 19, Amigo discloses the hydrophilic polymer comprising a plurality of amide groups, and being a polymerisate of monomers of acrylamide (i.e. polyacrylamide). (Column 5, lines 32-40)

Addressing claim 21, Amigo discloses covalent attachment between the hydrophilic polymer and the skeleton. (Column 4, lines 59-64)

Addressing claims 22 and 23, Amigo discloses the polymer skeleton being an organic polymer that is neutral. (Column 4, lines 32-40)

Addressing claim 28, Amigo discloses the surface of the planar substrate being made of a plastic that comprises a non-significant fluorescence for excitation wavelengths in the interval of 200-800 nm and emission wavelengths in the interval of 400-900 nm. (Column 3, line 36 - Column 4, line 9)

Addressing claim 31, Amigo discloses a microfluidic device (Column 6, line 46 - Column 8, line 21) comprising a set of one or more (Column 7, lines 29-34) covered microchannel structures (Column 7, lines 49-55) manufactured in the surface of a planar substrate (Column 3, line 36 - Column 4, line 9), wherein a part of the surface of at least one of the microchannel structures comprises a coat exposing a non-ionic hydrophilic polymer (Column 4, line 53 - Column 5, line 48), and the surface of the planar substrate is made of a plastic that comprises a non-significant fluorescence for excitation

wavelengths in the interval of 200-800 nm and emission wavelengths in the interval of 400-900 nm. (Column 3, line 36 - Column 4, line 9)

Addressing claims 32, 34, and 38, Amigo discloses the plastic substrate being based on a polymer of aliphatic monomers containing polymerizable carbon-carbon double bonds. (Column 3, lines 49-54)

Addressing claims 33, 35, and 39, Amigo discloses the monomer being ethylene or propylene. (i.e. product is polyethylene or polypropylene; Column 3, lines 49-54)

Addressing claim 36, Amigo discloses mass transport of solutes and/or particles between different functional parts of the microchannel structure using electroendoosmosis (i.e. electroosmotic flow, EOF). (Column 4, line 65 - Column 5, line 16; Column 6, lines 21-45)

Addressing claim 40, Amigo discloses the use of a coating of non-ionic hydrophilic polymer to modify the degree of non-specific adsorption and hydrophilicity within a microchannel. (Column 4, line 53 - Column 5, line 48) Regarding the question of optimization, generally, differences in concentration (i.e. in this case, density, thickness, or other variable of the coating) or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Addressing claim 41, Amigo discloses microchannel structures that comprise conduits for liquid transport. (Column 4, line 65 - Column 5, line 3)

Previous Claim Rejections - 35 USC § 103

15. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Amigo in view of the provided English translation of DE 197 53 847 (Zimmer et al).

Amigo discloses a device as described above in addressing claim 1.

Amigo does not explicitly disclose the surface having a sufficient hydrophilicity for liquid to enter the part once having passed the entrance of the part. (i.e. by capillary forces)

Zimmer et al disclose the ability of capillaries with sufficiently hydrophilic surfaces, including polymer surfaces, to draw in aqueous materials upon contact. (Pages 5-8)

It would have been obvious to one having ordinary skill in the art to modify the device of Amigo by providing a surface of sufficient hydrophilicity at a channel opening to draw aqueous fluids in by capillarity, as taught by Zimmer et al, because it would facilitate sample introduction in some applications. (e.g. biosensor)

16. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Amigo in view of Regnier et al.

Amigo discloses a device as described above in addressing claim 1.

Amigo does not explicitly disclose mass transport of solutes or particles between different functional parts of a microchannel structure using a liquid flow caused by non-electrokinetic forces.

Regnier et al disclose bulk fluid motion caused by non-electrokinetic means.
(Column 37, lines 53-59)

It would have been obvious to one having ordinary skill in the art to modify the device of Amigo by using a non-electrokinetic means of moving fluid within the channels, as taught by Regnier et al, because it would prevent electrophoretic bias in the injection procedure. Additionally, if the object of the application of the hydrophilic coating was to minimize or substantially eliminate electroosmotic flow (See Amigo, Column 5, lines 9-16), then a non-electrokinetic means of bulk fluid motion would be required in order to have efficient fluid flow.

17. Claims 12, 13, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amigo in view of Karger et al.

Amigo discloses a device as described in addressing claims 1 and 11 above.

Amigo does not explicitly disclose a device comprising a polyhydroxy hydrophilic polymer (Claim 12), a polyhydroxy polymer selected from among polysaccharides, polyvinyl alcohols, and poly(hydroxyl alkyl vinyl ether) polymers (Claim 13), or the device being in a dry state that is capable of being rehydrated. (Claim 29)

Karger et al disclose the use of a polyvinyl alcohol coating in electrophoresis capillaries in order to minimize adsorption of analytes to the capillary walls and control

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electroosmosis. (Column 1, line 50 - Column 2, line 39) (Claims 12 and 13) They also disclose the subsequent drying of the coated capillaries (Column 7, lines 1-39), and the rehydrating of the capillaries in later analyses. (Column 7, line 40 - Column 8, line 43) (Claim 29)

Addressing claims 12 and 13, it would have been obvious to one having ordinary skill in the art to modify the invention of Amigo by replacing his non-ionic hydrophilic coating with the polyvinyl alcohol coating taught by Karger et al, because Karger et al teach that it performs similar functions, and it would possess different reactivity that could facilitate a particular analysis.

Addressing claim 29, it would have been obvious to one having ordinary skill in the art to modify the invention of Amigo by providing the device in a dry state that is capable of being rehydrated, as taught by Karger et al, because it would facilitate device storage and shipping.

18. Claims 14 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amigo in view of Bergstrom et al. (US 5,250,613)

Amigo discloses a device as described in addressing claims 1 and 20 above.

Amigo does not explicitly disclose use of a hydrophilic polymer that is a reaction product between ethylene oxide and a dihydroxy or a polyhydroxy compound. (Claim 14) Amigo also does not explicitly disclose the use of a polyamine skeleton (Claim 24), a polyethylene imine skeleton (Claim 25), or a skeleton with a molecular weight of 10,000 - 3,000,000 Da. (Claim 26)

Relevant to claim 14, Bergstrom et al disclose the use of a coating of an adduct of ethylene oxide and a dihydroxy or polyhydroxy compound as a hydrophilic polymer that prevents or reduces analyte adsorption to a surface. (Column 7, lines 20-24; Column 1, line 56 - Column 2, line 28)

Relevant to claims 24-26, Bergstrom et al disclose the use of a polyethylene imine skeleton with molecular weight of 10,000 - 1,000,000 Da. (Column 3, lines 15-49; Column 7, lines 41-52) Polyethylene imine is a polyamine.

Addressing claim 14, it would have been obvious to one having ordinary skill in the art to modify the invention of Amigo by replacing his non-ionic hydrophilic coating with a coating of an adduct of ethylene oxide with dihydroxy or polyhydroxy compounds, as taught by Bergstrom et al, because Bergstrom et al teach that it performs similar functions, and it would possess different reactivity that could facilitate a particular analysis.

Addressing claims 24-26, it would have been obvious to one having ordinary skill in the art to modify the invention of Amigo by replacing his non-ionic hydrophilic coating with a biopolymer (e.g. cellulose, starch) coating supported by a skeleton of polyethylene imine with a molecular weight of 10,000 - 1,000,000, as taught by Bergstrom et al, because Bergstrom et al teach that it performs similar functions, and it would possess different reactivity that could facilitate a particular analysis.

19. Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amigo in view of Malmsten et al.

Amigo discloses a device as described in addressing claim 11 above.

Amigo does not explicitly disclose use of a polymer comprising one or more blocks of polyoxyethylene chains (Claim 15), the use of polyethylene glycol as the hydrophilic polymer (Claim 16), or the use of polyethylene glycol with a methoxy group at the end that does not bind to the surface as the hydrophilic polymer. (Claim 17)

Malmsten et al disclose the use of polyethylene glycol as a hydrophilic coating for minimizing protein adsorption in biological applications. (Abstract, Introduction) A variety of polyethylene glycol was disclosed that had methoxy end groups that do not bind the surface (Tables 2 and 3, Pages 512-515)

It would have been obvious to one having ordinary skill in the art to modify the invention of Amigo by replacing his non-ionic hydrophilic coating with the polyethylene glycol coating taught by Malmsten et al, because Malmsten et al teach that it performs similar functions, and it would possess different reactivity that could facilitate a particular analysis.

20. Claims 1 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karger et al in view of Van Alstine.

Relevant to claim 1, Karger et al disclose a microfluidic device (Column 2, lines 27-32) comprising a set of one or more covered microchannel structures (Column 9, line 18 - Column 10, line 4) manufactured in the surface of a planar substrate (Column 2, lines 27-32), wherein non-specific adsorption and hydrophilicity are altered by a coat

exposing a non-ionic hydrophilic polymer on a part of the surface of at least one of the microchannel structures. (Column 2, lines 20-39)

Relevant to claim 27, Karger et al disclose the substrate being made of plastic (Column 6, lines 15-22), and preparation of a bare capillary surface (silica) with acid to ensure proper surface functionalization for the coating reaction. (Column 7, lines 1-11)

Karger et al do not explicitly disclose the part surface without coat being hydrophilized by a plasma treatment or oxidation agent in order to introduce functional groups that allow for a subsequent attachment of a coat onto the part surface.

Relevant to claim 27, Van Allstine discloses the preparation of a plastic substrate for coating by plasma treatment, in order to introduce reactive surface groups. (Column 6, lines 14-21 and 31-39)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Karger et al by preparing the plastic substrate for coating by plasma treatment, as taught by Van Allstine et al, because it would provide a dry, less labor-intensive means of surface preparation.

Also regarding the question of optimization, generally, differences in concentration (i.e. in this case, density, thickness, or other variable of the coating) or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

21. Claims 1 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Regnier et al in view of Amigo.

Relevant to claim 1, Regnier et al disclose a microfluidic device (Column 35, line 6 - Column 36, line 53) comprising a set of one or more (Column 35, lines 53-59) covered microchannel structures (Column 36, lines 10-13) manufactured in the surface of a planar substrate (Figures 8 and 10), wherein non-specific adsorption and hydrophilicity are affected by a coat exposing a non-ionic hydrophilic polymer on a part of the surface of at least one of the microchannel structures. (Column 37, lines 12-29, especially line 27)

Relevant to claim 30, Regnier et al disclose a method of performing an analytical assay (Example 2) comprising preparing a sample (Column 42, lines 63-65); running an assay reaction (Column 42, line 65 - Column 43, line 7), and detecting the result of the assay reaction, wherein the result is a measure of the activity of the sample. (Column 43, lines 12-20)

Regnier et al do not explicitly disclose optimization of non-specific adsorption and hydrophilicity by the coat of the non-ionic hydrophilic polymer.

Amigo discloses the optimization of non-specific adsorption in conjunction with hydrophilicity in a device using the same and similar coatings (e.g. polyacrylamide) (Column 4, line 65 - Column 5, line 40) Also regarding the question of optimization, generally, differences in concentration (i.e. in this case, density, thickness, or other variable of the coating) or temperature will not support the patentability of subject matter

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encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the invention of Regnier et al by optimizing non-specific adsorption and hydrophilicity by the coat of the non-ionic hydrophilic polymer, as taught by Amigo, because it would reduce sample loss.

New Claim Objections

22. Claim 48 is objected to because of a typographical error. "Optimised" is misspelled as "optisimed" in line 2 of the claim. Appropriate correction is required.

New Claim Rejections - 35 USC § 112

23. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

24. Claims 1-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation to one or more "non-

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electrophoresis" microchannels is present in all presented claims as amended, and Applicants indicated support at page 2, 1st paragraph. However, the sentence running from lines 1-6 of page 2 indicates that *sole capillaries* as used in capillary electrophoresis are not devices as contemplated in the context of the invention. (Italics added) This does not indicate that electrophoresis in general is not contemplated within the claimed devices and methods.

New Claim Rejections - 35 USC § 102

25. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

26. Claims 42, 43, 47-49, 52, and 53 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Amigo.

Amigo discloses devices as described above in addressing claims 1 and 21.

Regarding claims 42 and 43, Amigo discloses inorganic materials and polymers for the channel surfaces. (Column 3, lines 8-19 and 47-49; glass is disclosed)

Regarding claim 47, Amigo discloses solute transport. (Column 4, line 65 - Column 5, line 3; EOF of the solution will lead to solute transport)

Regarding claim 48, Amigo discloses coating of a functional capillary and teaches means of optimization. (Column 6, lines 21-29; Column 5, lines 8-40)

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Regarding claims 49 and 52, Amigo discloses microchannel structures comprising volume-defining units. (Column 6, lines 21-29 - any defined channel or chamber structure will inherently define a volume)

Regarding claim 53, the slab gel chambers of Amigo would effect sample component separation. (Column 6, lines 21-29)

New Claim Rejections - 35 USC § 103

27. Claims 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amigo in view of Daecher et al.

Amigo discloses devices as described above in addressing claims 33, 35, and 39. Amigo discloses the suitability of a broad range of polymers for forming the substrate of his device, suggesting the use of other suitable materials ("and the like" - Column 3, lines 36-60)

Amigo does not explicitly disclose using a norbornene as a monomer.

Daecher et al disclose the preparation of polymer sheets suitable for forming microfluidic systems (Column 9, lines 55-65) using polymers made using norbornene monomers. (Column 14, lines 9-32)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Amigo by forming it using a polymer sheet made using norbornene monomers, as taught by Daecher et al, because Amigo suggested the use of other suitable polymers, and Daecher et al teach the suitability of these materials for forming microfluidic devices.

28. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Amigo in view of Karger et al.

Amigo discloses a device as described above in addressing claim 49.

The reasoning for this combination is as given above in addressing claim 29.

29. Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Amigo in view of Zimmer et al.

Amigo discloses a device as described above in addressing claim 49.

The reasoning for this combination is as given above in addressing claim 7.

Response to Arguments

30. Applicant's arguments filed 2 February 2005 have been fully considered but they are not persuasive. Due to the numerous grounds of rejection, the arguments are addressed below in the same order presented in Applicants' amendment.

Regarding the rejection of claims 1-6, 8, 10, 11, 18-23, 28, 31-36, and 38-41 under 35 U.S.C. §102(e) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over Amigo, applicant argues that Amigo teaches electrophoresis devices and methods, in contrast to the claimed "non-electrophoresis" devices and methods of the instant application. (Page 13, section III) The Examiner considers this new limitation to constitute new matter, as described above in paragraph 15.

Nevertheless, this limitation would still not distinguish the instant claims over Amigo, as a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Within Applicants' apparent definition, electroendosmotic fluid motion does not constitute an electrophoretic phenomenon. (Claim 36, which depends from claim 1, specifies electroendosmotic flow) Amigo clearly teaches electroendosmotic flow within his system (Column 4, line 65 - Column 5, line 3), showing that the system of Amigo is capable of performing according to the claim limitations.

Regarding the rejection of claim 7, in addition to the arguments concerning the "non-electrophoresis" limitation, Applicants argue that non-specific adsorption considerations were not addressed by Zimmer et al. (Pages 13-14, section IV-A) Zimmer et al was not relied upon to teach remedies to the problem of non-specific adsorption, but to teach fluid introduction through capillary forces. (i.e. "self-suction" as claimed) Applicants' arguments do not address this basis for combination of the references, and are therefore unpersuasive.

Regarding the rejection of claim 9, in addition to the arguments concerning the "non electrophoresis" limitation, Applicants assert that no teaching or suggestion is

present in Amigo and Regnier et al to arrive at the claimed invention. (Pages 14-15, section IV-B) On the contrary, the cited passage of Regnier teaches alternative means of fluid introduction and flow within a microfluidic system. In view of this teaching, a skilled artisan would recognize that an electrophoretic system (e.g. Amigo) could be modified to incorporate such flow means that are not electrokinetic.

Regarding the rejection of claims 12-17, 24-26, and 29, Applicants rely upon the arguments concerning the “non-electrophoresis” limitation (Pages 15-17, sections IV-C - IV-E), which was addressed in the first paragraph of this section.

Regarding the rejection of claims 1 and 27 under 35 U.S.C. §103(a) as obvious over Karger et al in view of Van Alstine, applicant argues that Karger and Van Alstine teach electrophoresis devices and methods, in contrast to the claimed “non-electrophoresis” devices and methods of the instant application. (Page 17, section IV-F) As stated above, the Examiner considers this new limitation to constitute new matter, as described above in paragraph 15. Nevertheless, this limitation would still not distinguish the instant claims over the prior art, as a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Within Applicants’ apparent definition, electroendosmotic fluid motion

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does not constitute an electrophoretic phenomenon. (Claim 36, which depends from claim 1, specifies electroendosmotic flow) Karger et al clearly teach that electroendosmotic flow occurs within their system (Abstract - EOF is minimized, not eliminated), showing that the system of Karger et al is capable of performing according to the claim limitations.

Regarding the rejection of claims 1 and 30 under 35 U.S.C. §103(a) as obvious over Regnier et al in view of Amigo, applicant argues that Regnier et al and Amigo teach electrophoresis devices and methods, in contrast to the claimed “non-electrophoresis” devices and methods of the instant application. (Page 17, section IV-G) As stated above, the Examiner considers this new limitation to constitute new matter, as described above in paragraph 15. Nevertheless, this limitation would still not distinguish the instant claims over the prior art, as a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Regnier et al clearly teach that non-electrophoretic movement and processes occur within their system (Column 37, lines 53-59; Column 37, lines 12-15), showing that their system is capable of performing according to the claim limitations.

Conclusion

31. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

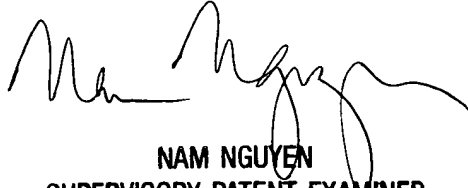
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

32. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Jeffrey Barton, whose telephone number is (571) 272-1307. The examiner can normally be reached Monday-Friday from 8:30 am – 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached at (571) 272-1342. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

JTB
March 17, 2005



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